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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,902	12/04/2001	Dale Brown	5369/00015	7185

22910 7590 06/02/2006

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,902	Applicant(s) BROWN ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **March 14, 2006** presents remarks and arguments to the office action mailed **December 20, 2005**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Status of claims:

Claims 2-7 and 9-14 are pending.

Claims 2-3, 7, 9-11 have been amended.

Claim 8 is withdrawn and claim 14 has been added.

Claims 2-7 and 9-14 are rejected.

Response to Amendment

Claim Objections

The objections made to claims 2 and 3 have been dropped.

Applicant traverses: that the Keller patent does not teach the use of "self " use of a syringe with regards to administering the tetracycline, and that the Kellers' patent teaches a methodology that is drastic, and not a simple routine readily practice at home.

In response, the argument is traversed, because the use of a syringe in the Kellers' patent is one embodiment of the patent of delivery of medicaments to periodontal patients. The claims are rejected based upon the fact that the teachings of Keller would have been obvious to one of ordinary skill in the art at the time the claimed

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invention was made. ". It is noted that the features upon which applicant relies (i.e., syringe) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. The claims are rejected based upon the limitations in the claims, and those limitations are set forth below in the rejection. Nowhere in the office action did it refer to application via syringe. Although, it is agreed, that the patent refers to the use of a syringe, even if this is so the patent clearly states "The provision of such a method of treatment wherein a patient can easily, without special training or undue skill, self-administer medication to the infected site so that the patient is not dependent upon a dentist or clinician to administer the medication and continue the treatment over an extended period" (Cir. 1993). The patent clearly teaches "self" administration of medicament to the tooth.

Applicant further traverses that the Hill references does not teach or suggest self treatment process for periodontal patients with gingival detachment of about 3 mm and greater, comprising the step of physically removing biofilms on a daily basis from supragingival, interproximal and subgingival tooth surfaces and simultaneously controlling inflammation related to heart disease as set forth in claim 2.

In response Hill teaches cleaning the gingival tooth surfaces with a toothbrush (at col.1 lines 65+), which corresponds to current claim 1. Controlling inflammation related with heart disease –Vascular dilation (see col. 2 lines 17-28) corresponds to instant claim 2). In addition, Hill teaches administering soft abrasives onto gingival surfaces-supragingival (col.2 lines 4-50) (on/base) and subgingival-deepened gingival

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sulcus (periodontal pockets) with a toothbrush. The reference also teaches the therapeutic substance consists of fluoride (see col. 10 lines 3-10) in current claims 12 and 13, which is directed to brushing with a channeled bristle toothbrush and a soft abrasive toothpaste (see col. 2 lines 57-60) corresponds to current claim 3.

Applicant also traverses that nothing in the Kim et al. patent teaches the claimed invention which is self-treatment process.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Kim et al. reference the subject matter of current claim 7, which is directed to adding an anti-inflammatory agent to the dentifrices (see col. 1 lines 54-65) where the therapeutic substance/agent is chlorohexidine gluconate, cetylpyrrolidinium chloride, triclosan (cited at col. 1 lines 54-57).

Applicant's arguments have been fully considered but they are not persuasive and the rejection is therefore maintained and hereby repeated.

Maintained Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller US 5,129,824 ('824) in view of Hill US 5,993,784 (784) and Kim et al US, 6,045,800 ('800) further in view of Petrus US 5,875,798 ('798).

Keller teaches a method to treat periodontal disease (at col. 2 lines 39-45), where the patient (self) can easily administer medication to the infected site (see col. 2 lines 49-60), as in the current claim 1, by physically removing biofilms (plagues) from the subgingival, supragingival and interproximal tooth surfaces on a daily basis (at col. 7 lines 20-32) by brushing, flossing or with an interdental brush (proxy brush) is taught (at col. 3 lines 4-19) as recited in instant claims 1 and 2 at least once a day (at col. 7 lines 20-32)

With regards to claim 3 and 5, the prior art reference of Keller et al. teach of a flossing device that contains a releasable therapeutic substance (at col. 3 lines 4-6, also at col. 5 lines 20+), where the floss is elastomeric material (at col. 3 lines 15-19) as depicted by current claim 6. The reference also teach the delivery of the therapeutic agent/substance (tetracycline) as does current claim 12 via brushing, where the medicament is applied by squeezing (see col. 5 lines 50 55) thus obviously teaching of a gel like paste as in current claim 4.

With regards to claims 9-11, the reference did not per se teach the use of at least two or three dental devices more than once a day or used after every meal. However, the reference teaches the use of more than one device while treating the patient in need thereof (see examples 2-5 columns 7-8) i.e., using a floss for a duration of time, and then a brush or a tray. One of ordinary skill in the art would have been motivated to use more than one dental device per day, where brushing (the supragingival surface) takes place in the morning, flossing in between meals approximately three times a day, as this will help prevent food particles in the interproximal and subgingival or proxy brushing because brushing and flossing are commonly practiced daily, which is yet another well known practice to skilled in the art.

Hill teaches cleaning the gingival tooth surfaces with a toothbrush (at col.1 lines 65+), which corresponds to current claim 1. Controlling inflammation related with heart disease –Vascular dilation (see col. 2 lines 17-28) corresponds to instant claims 2 and 7). In addition, Hill teaches administering soft abrasives onto gingival surfaces- supragingival (col.2 lines 4-50) (on/base) and subgingival-deepened gingival sulcus

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(periodontal pockets) with a toothbrush. The reference also teaches the therapeutic substance consists of fluoride (see col. 10 lines 3-10) in current claims 12 and 13, which is directed to brushing with a channeled bristle toothbrush and a soft abrasive toothpaste (see col. 2 lines 57-60) corresponds to current claim 3.

Kim et al. teach the subject matter of current claim 7, which is directed to adding an anti-inflammatory agent to the dentifrices (see col. 1 lines 54-65) where the therapeutic substance/agent is chlorohexidine gluconate, cetylpyrridium chloride, triclosan (cited at col. 1 lines 54-57).

Petrus teaches therapeutic use of tooth picks in treating periodontal disease that may predispose individuals with cardiovascular disease (heart) as in instant claims 2, 7 and 19. Cardiovascular disease is defined as relating to, or involving the heart and the blood vessels: (*cardiovascular disease*).

Although, the above cited references ('824, '784 and '798) did not per se teach the combination of using two or more devices per day or the use of at least one device after every meal, it would have been obvious to one of ordinary skill in the art to self administer-thus self treating periodontal disease that is associated with heart disease using a tooth brushing device in the morning to deliver the therapeutic agent. One of ordinary skill in the art would have been motivated to use a flossing device between meals because this device (floss) can be easily carried with the patient anywhere, and use at any time desired thus providing and facilitating the skilled artisan with motivation to use the floss device and deliver the therapeutic agent at various intervals including increased, modes and frequencies of administration.

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Moreover, it is well within the level of one having ordinary skill in the art to be motivated to use more than one device a day to maximize the effect of the drug as this would prevent surgery to the affected area (see the examples in cols.7 and 8) of the '824 reference. It is also a way of continuous treatment, which is particularly important to the treatment of the disease or affected area, which is yet another well known practice to skilled in the art.

One of ordinary skill in the art would have combined the '824, '784 references with that of '800, by adding the anti-inflammatory agent to the gel (see col. 2 lines 1-15) at the time the claimed subject matter was made, because it will inhibit the production of the prostaglandins, which is an inducing agent for periodontal disease. The reference '824 also teaches the addition of other medicaments to the dental device (see col. 7 lines 35-40 of the '824 reference), therefore one of ordinary skill in the art would have been motivated to add an anti-inflammable active agent to the delivery device in order to decrease the prostaglandins production and inflammatory activity as well as expecting a successful result in doing so.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
12/01/05

 5/30/06
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SUPERVISORY PATENT EXAMINER